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Does HIV Pre-Exposure Prophylaxis Use Lead to a Higher Incidence of Sexually Transmitted Infections? A Case-Crossover Study of Men Who Have Sex with Men in Los Angeles, California

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Abstract

Background—Pre-exposure prophylaxis (PrEP) is an effective method for reducing HIV incidence among at-risk populations. However, concerns exist over the potential for an increase in sexually transmitted infections (STIs) following PrEP initiation. The objective of this study is to compare the STI incidence before and after PrEP initiation within subjects among a cohort of men who have sex with men (MSM) in Los Angeles, California.

Methods—The present study used data from patients who initiated PrEP services at the Los Angeles LGBT Center between October 2015 and October 2016 (n = 275). A generalized linear

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MAD - Study concept, data cleaning, design, analysis, and manuscript review
REW - Study concept, design, analysis, and manuscript review
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mixed model was used with a case-crossover design to determine if there was a significant difference in STIs within subjects 365 days before (before-PrEP period) and 365 days after PrEP initiation (after-PrEP period).

Results—In a generalized linear mixed model, there were no significant differences in urethral gonorrhea (p = 0.95), rectal gonorrhea (p = 0.33), pharyngeal gonorrhea (p = 0.65), or urethral chlamydia (p = 0.71) between periods. There were modest increases in rectal chlamydia (RR: 1.83; 95% CI: 1.13–2.98; p = 0.01) and syphilis diagnoses (RR: 2.97; 95% CI: 1.23–7.18; p = 0.02).

Conclusions—There were significant increases in rectal chlamydia and syphilis diagnoses when comparing the periods directly before and after PrEP initiation. However, only 28% of individuals had an increase in STIs between periods. Although risk compensation appears to be present for a segment of PrEP users, the majority of individuals either maintain or decrease their sexual risk following PrEP initiation.

INTRODUCTION

Pre-exposure prophylaxis (PrEP) is a biomedical prevention strategy where HIV-negative individuals take a once daily antiretroviral pill to prevent contracting HIV. Multiple randomized controlled trials have demonstrated that PrEP can effectively reduce the incidence of new HIV infections between 44% to 75% among different populations of high-risk uninfected individuals (1–6). The first large cohort study of PrEP efficacy found a 44% reduction in the incidence of HIV between the treatment and placebo groups among persons engaging in high-risk sexual behaviour (1). A second study found that the incidence of HIV was 1.2 infections per 100 person-years in the treatment group versus 9 infections per 100 person-years in the group that received deferred PrEP (7).

The success of PrEP in these large-scale trials prompted the U.S. Centers for Disease Control and Prevention (CDC) to recommend PrEP initiation for individuals at increased risk for HIV exposure, including sexually active, HIV-negative gay, bisexual, and other men who have sex with men (MSM). The CDC indicates PrEP use for MSM meeting at least one of the following criteria in the past six months: 1) engaging in any condomless anal intercourse, 2) having had any diagnosis of a sexually transmitted infection, and/or 3) being in an ongoing sexual relationship with an HIV-positive partner (8).

An analysis by the CDC found that 25% of HIV-negative MSM in the United States between the ages of 18–59 met the CDC guidelines for PrEP use (9). However, the latest published data show that only between 4% and 10% of MSM report using PrEP (10, 11).

Slow adoption of PrEP may be due to numerous factors including concerns held by both potential PrEP users as well as by prescribing physicians. Reservations about taking PrEP at the patient level include both short-term and long-term drug side effects (12–15), out of pocket costs (12, 13, 15, 16), the possibility for drug resistance given PrEP continuation following HIV infection (13), and fear of being stigmatized as promiscuous (17).

A recent survey of physicians that asked about their willingness to prescribe PrEP reported that 96% of respondents noted concerns about patient adherence to the regimen (18). Other

studies of physician attitudes have cited similar adherence concerns (19, 20) as well as concerns that PrEP users may be more likely to forego using condoms once on PrEP, leading to higher incidence of other sexually transmitted infections (STIs) (18, 21).

The concept of exhibiting greater sexual risk after adoption of a safety measure like PrEP is known as risk compensation or risk homeostasis. A study by Brooks et al. in 2012 found that 60% of HIV-negative MSM surveyed (n = 25) said they would either decrease or abandon condom use with the adoption of PrEP (22). However, other studies have found contrary results, with potential PrEP users stating that they would not be likely to reduce condom use (23, 24). Additionally, a large cohort study of PrEP users over the first nine months of use found that users reported the same amount or fewer sex partners over follow-up when compared to baseline (25). While self-reported intentions following PrEP use and risk behaviour assessments are informative, measuring biomarkers like STIs may be a more objective indicator of risk compensation among PrEP users.

Three studies have examined STIs among PrEP users. McCormack et al. compared the STI incidence between PrEP users and non-PrEP users and found no differences between the groups (7). A second study found that after six and twelve months of PrEP use, 30% and 50% of PrEP users had been diagnosed with any STI, respectively (26). A third study found that 35% of PrEP users were diagnosed with an STI during follow-up (27).

These studies were limited in that they only examined STI rates after PrEP use and therefore did not control for STI rates among the same individuals prior to initiating PrEP. By comparing STIs within subjects, between-person confounders are greatly minimized and a more rigorous assessment of STI changes can be performed. The primary objective of this study is to use a case-crossover design to determine if there is a difference in STIs in the periods before and after PrEP for each subject analyzed. The secondary objective is to determine if there are any behavioural differences between individuals who exhibit an increase in STIs versus individuals who demonstrate either no change or a decrease in STIs in the periods before and after PrEP initiation.

MATERIALS AND METHODS

The Los Angeles LGBT Center (the Center) is a Federally Qualified Health Center located in the Hollywood neighborhood of Los Angeles, California. The Center offers HIV/STI testing, transgender healthcare services, primary healthcare, HIV care, and biomedical prevention services (e.g., PrEP). The Center began prescribing PrEP through its West Hollywood (Center WeHo) satellite location in October 2015.

All patients who receive HIV/STI testing through the Center WeHo are administered a baseline risk assessment to determine demographics, recent sexual behaviour, substance use behaviours, and knowledge of non-occupational post-exposure prophylaxis (PEP) and PrEP. For those who do not report already taking PrEP, HIV/STI testing counselors provide education about PrEP and ask patients about both their self-perceived candidacy for PrEP and their likelihood to initiate PrEP.

Patients who indicate a desire to initiate PrEP are referred to a PrEP linkage coordinator to set up the initial appointment with a PrEP provider. Each patient is evaluated to rule out any medical contraindications to PrEP, including prevalent or incident HIV infection. Labs are subsequently taken for STIs (gonorrhea, chlamydia, and syphilis), Hepatitis B, Hepatitis C, and renal function. Patients are educated about medication adherence and side effects, and a 30-day prescription is written for PrEP, following provider approval. To continue receiving PrEP prescriptions, patients are required to return 30 days after the baseline visit, and every three months thereafter, for HIV and STI testing, lab review to measure renal function, and review of medication adherence.

At baseline and follow-up visits, patients are asked to self-collect urine and rectal specimens for gonorrhea and chlamydia testing. A lab technician then swabs the throat to test for gonorrhea and takes a blood sample to test for syphilis, HIV, and renal function. The blood sample is also used to test for HIV antibodies through an HIV rapid test. Individuals who test HIV antibody negative have a nucleic acid amplification test (NAAT) which is sent for acute HIV screening. Individuals who are positive for any STI except HIV are called back for treatment typically within two to seven days. Individuals who test positive for HIV are taken off PrEP and immediately linked to HIV care by an HIV linkage-to-care specialist.

The inclusion criteria for this analysis are 1) men who have sex with men (MSM), 2) initiation of a PrEP regimen at the Center's Sexual Health and Education Program between October 2015 and October 2016, 3) at least one STI testing visit within 365 days prior to PrEP initiation, 4) at least one STI testing visit within 365 days after PrEP initiation, and 5) no previous reported use of PrEP or PEP before initiating PrEP at the Center. An MSM is defined as an individual who was assigned a male sex at birth, reported that their gender identity is male, and either reported a sexual orientation of gay or bisexual or reported sex with a man at the last sexual encounter. Follow up STI testing data were available up to the end of May 2017.

Statistical Methods

This study uses a case-crossover design with an intent-to-treat analysis to assess changes in STI incidence between the period prior to PrEP initiation (before-PrEP) and the period after PrEP initiation (after-PrEP). The case-crossover design has each individual serving as their own control (also known as an interrupted time series design). The before-PrEP period consists of any STI testing visits in the 365 days prior to PrEP initiation as well as the STI testing visit during the PrEP enrollment visit. The after-PrEP period consists of the STI testing visits up to 365 days after PrEP initiation. However, not all individuals have 365 days of data as only those who started PrEP in May 2016 or earlier could have complete data. An intent-to-treat design was used since reliable biological measures of PrEP adherence (intraerythrocytic tenofovir diphosphate levels in dried blood spots) were not taken for individuals receiving PrEP.

We analyze all body site/STIs in a single model. A generalized linear mixed model (GLMM) with a person-random effect is used to determine the rate ratio of STI incidence in the period after PrEP to the period before PrEP. Predictors in the model include the period variable (before- or after-PrEP) and the bodily site/STI tested (e.g., urethral gonorrhea, rectal

chlamydia) and the interaction between these two variables. The effects of interest are the STI rate ratio of the STI rate after PrEP initiation to the STI rate before PrEP initiation. The outcomes for each person contained results of STI testing for each possible bodily site/infection combination: urethral gonorrhea, rectal gonorrhea, pharyngeal gonorrhea, urethral chlamydia, rectal chlamydia, and syphilis. The GLMM was a log link random intercept Poisson model with log of time since last visit as an offset (subsequently referred to as the Poisson GLMM). We included age group, race/ethnicity, and sexual orientation in the base model to estimate STI rate differences across demographic groups.

We fit a second GLMM model with indicators of the before- and after-PrEP periods as covariates, and the number of visits in each period as the outcome, to determine if detection bias was potentially present. Lastly, we compared individuals who had an increase in STIs with individuals who had no change or a decrease in STIs to determine if there was a difference in either self-reported substance use or the number of sexual partners in the past three months. All analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC).

Ethics

The study received approval from the University of California, Los Angeles South General Institutional Review Board (SGIRB) (IRB Number: 00004474; Project Number: 16–000452).

RESULTS

Two hundred and seventy-five individuals met the inclusion criteria for analysis. The majority of the sample was between the ages of 30 and 39 at baseline, White or Latino, gay, and reported having a college degree or higher (Table 1).

The before-PrEP period had a lower number of STI testing visits (n = 755) when compared to the after-PrEP period (n = 908) (Table 2A). Overall gonorrhea prevalence decreased from 11.7% in the before-PrEP period to 10.3% in the after-PrEP period. In contrast, syphilis prevalence increased from 1.5% to 3.5%. Chlamydia prevalence remained unchanged at 9.6% and prevalence for gonorrhea, chlamydia, and/or syphilis (any STI) remained the same at approximately 20%. Similar results were seen for gonorrhea, chlamydia, and syphilis incidence (Table 2B).

In the Poisson GLMM, there were no significant differences in urethral gonorrhea ($p = 0.95$), rectal gonorrhea ($p = 0.33$), pharyngeal gonorrhea ($p = 0.65$), or urethral chlamydia ($p = 0.71$) between periods (Table 3). There was an 29% increase in rectal chlamydia ($p = 0.01$) and 164% increase in syphilis diagnoses ($p = 0.02$). There were no significant differences in STIs by age group ($p = 0.39$), race/ethnicity ($p = 0.14$), or sexual orientation ($p = 0.92$). In a second model, there was a significant increase in any STI from the before- to the after-PrEP periods (Rate Ratio = 1.36; 95% CI: 1.06–1.74; $p = 0.02$).

To determine if detection bias was present in this analysis (i.e., detection of more STIs as an artifact of more STI testing), we used a second GLMM to determine if there was a difference in the number of visits per unit time between periods. There was a modest 7% decrease in

the average number of STI testing visits from the before-PrEP period (Mean = 2.72; Median = 2; SD = 1.7) to the after-PrEP period (Mean = 2.52; Median = 2; SD = 1.7) ($p < 0.0001$).

Of the 275 unique individuals in the analysis, the plurality were not diagnosed with STIs in either the before or after period (38%) followed by individuals who had an increase in STIs (28%), a decrease in STIs (24%), and the same number of STIs in the before and after periods (10%). When comparing individuals who had an increase in STIs and individuals with no STIs, a decrease, or no change, there were no differences by self-reported methamphetamine use ($p = 0.59$), nitrates use ($p = 0.42$), ecstasy use ($p = 0.15$), and number of sexual partners in the past three months ($p = 0.34$).

DISCUSSION

Our study showed that there were no significant differences in urethral gonorrhea, rectal gonorrhea, pharyngeal gonorrhea, or urethral chlamydia between the before- and after-PrEP periods. In contrast, there was a 29% and 164% increase in rectal chlamydia and syphilis, respectively, between periods. When analyzing any STI as an outcome, there was a significant overall increase in STIs between periods. To the best of our knowledge, this is the first study to compare each patient's STI testing results before and after PrEP initiation to determine if there was a true change in STIs.

The increase in syphilis between periods may be partly explained by two factors. First, syphilis chancres may be in areas not covered by a condom during intercourse, and therefore transmission may occur despite a condom being used (28). Second, this finding is consistent with an overall upward trend in syphilis seen in the population of patients testing for STIs at the Center who are not using PrEP. In the year before PrEP was prescribed at the Center (November 2014 to October 2015), syphilis positivity among non-PrEP users was 2.9%. In the next year (November 2015 to October 2016), syphilis positivity increased to 3.4% among non-PrEP users. Therefore, there appears to be an overall increase in syphilis diagnoses, regardless of PrEP use.

The increasing overall trend was not observed in the general population for rectal chlamydia in the years before and after PrEP initiation at the Center. Rectal chlamydia in the periods before and after PrEP availability at the Center in the non-PrEP population remained consistent at 9.8%. Further studies in other jurisdictions should replicate these analyses to determine if our finding of an increase in rectal chlamydia is an aberration or an actual trend.

Our study has notable limitations. Although we included all STI testing visits up to 365 days after PrEP initiation, a full 365-day period was not available for all patients included in the analysis since the analysis period ended in May 2017. For example, an individual who began PrEP in October 2016 would only have contributed eight months to the after-PrEP period. However, our protocols require patients to return at three month intervals to refill their PrEP prescription, and a majority of individuals included had at least two STI testing visits in the after-PrEP period. Furthermore, we adjusted for time under observation by fitting incidence models. A second limitation is that the results may have been different had we included individuals who had previously used PEP or PrEP. We hypothesized that individuals who

have taken PEP or PrEP in the past are fundamentally different because they have prior experience with the medication. A third limitation is that we were unable to account for individuals who initiated PrEP and failed to take their medication yet still had STI testing. While this scenario is possible, our PrEP providers indicated that this was rare in the population included. A fourth limitation is that the case-crossover study design is observational and non-randomized. Furthermore, it is possible that changes in STI incidence may be attributable to factors beyond PrEP use. Lastly, the Center tests all PrEP patients for pharyngeal chlamydia, but this testing is not standard testing for non-PrEP patients. Therefore, we were unable to analyze changes in pharyngeal chlamydia since no data in the before-PrEP period was available.

Our study also had important strengths. The first strength is that this is the first study, to our knowledge, that had STI testing data both before and after PrEP initiation on the same individuals. Thus, we were able to use an individual's STI testing data before PrEP as a control to determine if STIs increased after starting PrEP.

The second strength of our study was the design of the PrEP protocol, which required patients to return at three month intervals to renew their PrEP prescription. Regularly testing at three-month intervals not only provides more complete STI data collection, but it also assures a better standard of care for the patient. Data from PrEP users receiving services at Callen-Lorde Community Health Center showed that 77% and 68% of STIs at three months and nine months, respectively, after starting PrEP would have been missed if providers relied solely on symptom assessment (29). Although the CDC recommends testing for STIs at six-month intervals, the data from the current study and the study conducted at the Callen-Lorde Community Health Center show that three-month intervals will help ensure timely treatment of STIs. Provided other clinics decide to implement similar PrEP protocols, mandatory testing as a condition for continuation of PrEP use will help protect both the patient and their partners from preventable STI morbidity.

Importantly, we found a non-monotonic trend in STI incidence between periods. A small segment of PrEP users had a higher number of STIs in the year following PrEP initiation (28%), a finding suggestive of risk compensation, while the remainder either had the same number of STIs as before or had a reduction in STIs, although this may be partly explained by the somewhat limited follow-up after PrEP initiation as compared to the longer run-up prior to PrEP initiation. While we were not able to detect differences by demographics, substance use, or number of sexual partners, there may be unmeasured behavioural predictors (e.g., percentage of sexual experiences where a condom was used) or psychological factors (e.g., sexual compulsivity, depression) that distinguish PrEP users who contract a greater number of STIs after PrEP initiation from PrEP users who maintain or lower their sexual risk profile. Future studies should analyze the roles of substance use, sexual compulsivity, and partner networks among PrEP users to more closely determine what factors lead to a higher incidence of STIs following PrEP initiation.

PrEP is an effective method for reducing the incidence of HIV, but vigilance is needed to keep the threat of other STIs at bay. As PrEP use becomes more widespread, prompt identification and treatment of STIs is necessary to prevent forward transmission of STIs.

Expansion of PrEP access, identification of those at highest risk for STI acquisition, STI testing requirements at three-month intervals, and continuing to identify early HIV infections to quickly initiate treatment could comprise an effective HIV and STI strategy in this new era of biomedical prevention.

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KEY MESSAGES

- Among MSM PrEP users in Los Angeles, there was no change in gonorrhea or urethral chlamydia from the year before to the year after PrEP initiation.
- There was a modest increase in syphilis and rectal chlamydia from the year before to the year after PrEP initiation.
- There was a non-monotonic trend in STIs in the periods before and after PrEP initiation among MSM in Los Angeles.

Table 1 -

Demographics of Men who Have Sex with Men Administered PrEP at the Los Angeles LGBT Center (n = 275) October 2014 - May 2017.

Demographic	n	%
Age Group		
<25	45	16.4%
25–29	72	26.2%
30–39	78	28.4%
40–49	30	10.9%
50+	20	7.3%
Unknown/Declined	30	10.9%
Race/Ethnicity		
White	126	45.8%
Hispanic or Latino	58	21.1%
Black or African American	18	6.5%
Asian/PI	13	4.7%
Native American	2	0.7%
Other	15	5.5%
Unknown/Declined	43	15.6%
Sexual Orientation		
Gay/Homosexual	222	80.7%
Bisexual	17	6.2%
Heterosexual	1	0.4%
Other	1	0.4%
Unknown/Declined	34	12.4%
Education Level		
Some High School or Lower	8	2.9%
High School Grad/GED	21	7.6%
Some College	42	15.3%
College Degree	125	45.5%
Post-Graduate	36	13.1%
Unknown/Declined	43	15.6%
Total	275	100.0%

Table 2A -

Prevalence of STIs in the 365 Days before and after PrEP Initiation (n = 275), October 2014 - May 2017.

	Up to 365 Days before PrEP*			Up to 365 Days after PrEP		
	Positive	**Total Tests**	**% Positivity**	**Positive**	**Total Tests**	**% Positivity**
Gonorrhea **						
Urethral	14	723	1.9%	15	843	1.8%
Rectal	52	706	7.4%	60	851	7.1%
Pharyngeal	52	721	7.2%	45	846	5.3%
Chlamydia **						
Urethral	21	723	2.9%	18	843	2.1%
Rectal	55	708	7.8%	71	851	8.3%
Syphilis	11	718	1.5%	29	823	3.5%
Gonorrhea, Chlamydia, and/or Syphilis	149	755	19.7%	182	908	20.0%

* The day that an individual began PrEP is counted in the “Before PrEP” category.

** Standard protocol requires testing at all sites, but individuals may not return all specimens. Differences in denominators are due to individuals not completing all tests as directed.

Table 2B -

Incidence of STIs in the 365 Days before and after PrEP Initiation (n = 275), October 2014 - May 2017.

	Up to 365 Days before PrEP*			Up to 365 Days after PrEP		
	Positive	**Person-Years**	**STIs per 100 Person-Years**	**Positive**	**Person-Years**	**STIs per 100 Person-Years**
Gonorrhea**						
Urethral	14	92.11	15.20	15	167.47	8.96
Rectal	52	91.95	56.55	60	167.58	35.80
Pharyngeal	52	92.69	56.10	45	167.87	26.81
Chlamydia**						
Urethral	21	92.11	22.80	18	167.47	10.75
Rectal	55	92.02	59.77	71	167.58	42.37
Syphilis	11	92.14	11.94	29	164.31	17.65
Gonorrhea, Chlamydia, and/or Syphilis	149	93.60	159.19	182	168.93	107.74

* The day that an individual began PrEP is counted in the “Before PrEP” category.

** Standard protocol requires testing at all sites, but individuals may not return all specimens. Differences in denominators are due to individuals not completing all tests as directed.

Table 3 -

Poisson Generalized Linear Mixed Model Comparing Each STI in the 365 Days Before PrEP and the 365 Days after PrEP (n = 275), October 2014 - May 2017.*

	Estimate	Standard Error	Rate Ratio (95% CI)	p-value
Gonorrhea				
Urine	−0.03	0.42	0.97 (0.42–2.23)	0.95
Rectal	0.23	0.24	1.26 (0.79–2.00)	0.33
Throat	−0.11	0.24	0.90 (0.56–1.44)	0.65
Chlamydia				
Urine	0.15	0.41	1.17 (0.52–2.61)	0.71
Rectal	0.61	0.25	1.83 (1.13–2.98)	0.01
Syphilis	1.09	0.45	2.97 (1.23–7.18)	0.02

* The period before PrEP is the reference group; negative coefficients indicate a decrease in STIs between periods; positive coefficients indicate an increase in STIs between periods.